In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

SANDY GINSBERG,	*	
	*	No. 19-222V
Petitioner,	*	Special Master Christian J. Moran
	*	
v.	*	
	*	Filed: July 31, 2024
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Amy Senerth, Muller Brazil, Dresher, PA, for petitioner;
Elizabeth Andary, United States Dep't of Justice, Washington, DC, for respondent.

PUBLISHED DECISION AWARDING COMPENSATION[1]

Sandy Ginsberg alleged that the influenza ("flu") vaccine damaged her left shoulder. She alleged both an on-Table claim that the vaccine caused her to suffer a left shoulder injury related to vaccine administration ("SIRVA") and an off-Table claim that the vaccine was the cause-in-fact of her shoulder problem. Am. Pet., filed Oct. 29, 2021. The Secretary disputed this allegation, contending that Ms. Ginsberg failed to either establish that her SIRVA was a Table injury or demonstrate that the flu vaccine caused-in-fact her left shoulder injury. Am. Resp't's Rep., filed Nov. 22, 2021. The Secretary claimed that she, instead, suffered from cervical radiculopathy and age-related tears in her rotator cuff. Id. The parties developed their positions by presenting expert reports, arguing through

[1] Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

legal memoranda, and presenting oral testimony. Ms. Ginsberg's expert is Dr. Natanzi. The Secretary's experts are Dr. Callaghan and Dr. Cagle.

For the reasons explained below, the evidence preponderates in favor of finding that Ms. Ginsberg established that the flu vaccine harmed her. A reasonable amount of compensation for this injury is $40,000.

I. Facts

A. Before Vaccination

Ms. Ginsberg was born in 1949. Before receiving the flu vaccine, she had a history of pain in her lower back and entire right lower extremity (right hip, right thigh and buttocks). Exhibit 5 at 2. She described the pain in all extremity locations as "aching, gnawing, and shooting." Id. From April 4, 2016 to June 13, 2016, she attended nine physical therapy sessions for her right hip. Exhibit 2 at 1-49. The medical records from 2015 and 2016 do not indicate any left shoulder pain or cervical spine issues. See Exhibit 5; Exhibit 2; see also Tr. 14, 104, 355.

She was 67 years old in January 2017 when she received the vaccination. She was relatively active, working part-time as a clerk in a library and exercising at a gym about two times per week. Tr. 13, 39, 64-65.

B. Vaccination

Ms. Ginsberg received the flu vaccine in her left deltoid on January 9, 2017. Exhibit 1. She recalled that during the administration of the vaccine, she was sitting and the administrator may have been standing. Tr. 14-15.

Ms. Ginsberg's shoulder pain developed within 48 hours of her vaccination. Tentative Finding, issued June 12, 2023. The evening of the vaccination, Ms. Ginsberg rated her pain as an "8" and then increased to a "10" in the days that followed. Tr. 15-16. She took some left-over pain medication, but the pain was so excruciating that her sleep was disrupted. Tr. 16-17, 55.

C. January 19, 2017: Dr. Ionescu

Medical Records

On January 19, 2017, Ms. Ginsberg saw her usual doctor at All Family Medicine, Dr. Danita Ionescu, and complained of numbness and pain in her left arm after receiving the flu vaccine ten days ago. Exhibit 42 (Dr. Ionescu's medical record); Exhibit 43 (transcript of Dr. Ionescu's medical record). Dr. Ionescu noted

that Ms. Ginsberg was concerned with a clot in her left arm and Dr. Ionescu observed that "her pain comes from the cervical spine on exertion." Id. Dr. Ionescu also noted: "Walked in, had flu shot and concerned she should sue (No reason), Million hearts, Doppler [left] arm – [negative] for [deep vein thrombosis], Osteoporosis, Neuropathy/Radiculopathy, Muscle Spasm, Cervical Strain, Flex[e]ril 10mg QHS, Naproxen 500 mg bid, Send for PT, Next visit – chronic conditions." Id.[2]

Ms. Ginsberg's Testimony

Ms. Ginsberg sought treatment from Dr. Ionescu. In her opinion, Dr. Ionescu is a good listener. Tr. 71.

Ms. Ginsberg told Dr. Ionescu about the flu shot and that pain in her arm was radiating to her neck. Tr. 19. She remembers more pain than numbness. Tr. 41. Ms. Ginsberg did not recall Dr. Ionescu physically examining her shoulder or neck, but Dr. Ionescu might have touched her. Tr. 21, 43. Dr. Ionescu referred Ms. Ginsberg for physical therapy. Tr. 43.

Expert Commentary

Dr. Natanzi

During Ms. Ginsberg's direct examination, she elicited relatively little testimony from Dr. Natanzi. Thus, most of Dr. Natanzi's testimony about Ms. Ginsberg's visit with Dr. Ionescu was during cross-examination.

Dr. Natanzi acknowledged that Dr. Ionescu's record does not refer to Ms. Ginsberg's arm being red or being swollen. Tr. 152. Dr. Natanzi similarly agreed that Dr. Ionescu's note does not suggest an acute trauma. Tr. 153, 197. This lack of external signs did not concern Dr. Natanzi. In his view, when people suffer shoulder injuries induced by vaccine administration, their arms do not look abnormal. Tr. 154. Dr. Natanzi has not opined that the flu vaccine caused Ms. Ginsberg to suffer cellulitis or an injury that would cause warmth or swelling. Tr. 153.

[2] A left upper extremity arterial duplex sonography from that day showed mild atherosclerotic plaguing. Exhibit 11 at 5. The interpreting physician concluded that the arterial study was normal. Id. According to the experts, searching for a blood clot was reasonable. Tr. 134 (Dr. Natanzi), 349 (Dr. Cagle).

Dr. Callaghan

Dr. Callaghan testified that Dr. Ionescu's record discusses numbness, which is associated with cervical radiculopathy. It does not discuss shoulder pathology. Tr. 259.

Dr. Cagle

Like Dr. Natanzi, Dr. Cagle's testimony about Dr. Ionescu's medical record came on cross-examination. In this context, Dr. Cagle acknowledged that Dr. Ionescu's medical record does not contain a line stating that she examined Ms. Ginsberg's shoulder. Tr. 351-53. However, Dr. Cagle remarked that Dr. Ionescu's record states that Ms. Ginsberg's "pain comes from the cervical spine." Tr. 352; see also Exhibit 43 at 2.

Dr. Cagle testified that based upon his research, a person with a shoulder injury due to vaccination often seeks treatment within the first two weeks after the vaccination. Tr. 398-99; see also Exhibit A-7. (Cagle, Shoulder Injury after Vaccination: A Systematic Review). Thus, Ms. Ginsberg's presentation within 10 days of the vaccination did not concern him. Tr. 398.

D. Physical Therapy

Medical Records

On January 24, 2017, Lori Karchinski, a physical therapist, evaluated Ms. Ginsberg's cervical radiculopathy and shoulder pain. Exhibit 2 at 52. Ms. Ginsberg reported that she has had "excruciating throbbing pain in her arm radiating to her neck and down into her hand" since her flu vaccine and suspected the pain was secondary to getting a flu shot. Id. at 52, 53. Ms. Ginsberg reported that she had difficulty dressing herself and was unable to shelve books in the library. Id. The results of the Hawkins-Kennedy and "empty can" tests were negative. Id. at 55. The Hawkins-Kennedy test (sometimes referred to as just the "Hawkins test") is an impingement test where the back of the shoulder is stabilized and the arm is moved to cause an internal rotation. The movement causes the rotator cuff and bursa to be pinched under the bone. If there is anything wrong, the test will cause pain. Tr. 212-23.

The empty can test traditionally involves putting the arm in a position as if one is emptying a can, and then somebody resists the upward force to test the supraspinatus tendon. A tearing of the supraspinatus and infraspinatus would be expected to yield a positive empty can test. Tr. 119. Ms. Karchinski stated that

Ms. Ginsberg had "signs and symptoms consistent with a diagnosis of cervical [radiculopathy] and left shoulder pain" and recommended "skilled physical therapy" three times a week for four weeks.[3] Id. at 55, 57.

Ms. Ginsberg's Testimony

Ms. Ginsberg had received care from Ms. Katchinski when Ms. Ginsberg had her hip treated. Tr. 44. Ms. Ginsberg felt comfortable being honest with her. Id.

In the subjective account, Ms. Katchinski memorialized that Ms. Ginsberg "reports date of injury to be 1/16/17." Exhibit 2 at 52. However, Ms. Ginsberg did not recall providing that information. Tr. 23. Ms. Ginsberg did recall telling Ms. Katchinski that the "mechanism of injury was secondary to getting flu shot." Exhibit 2 at 52; see also Tr. 23.

Ms. Ginsberg agreed that the document reflects that she was having pain in her left shoulder. Tr. 23; see also Exhibit 2 at 52. Ms. Ginsberg recalled that much of the physical therapy was for her neck, not her shoulder. Id. at 25. She stopped attending physical therapy on February 7, 2017. Exhibit 2 at 73. Ms. Ginsberg stated that she believed the physical therapy on her neck was not helping with the shoulder pain. Tr. 25.

Expert Commentary

Dr. Natanzi

A portion of the cross-examination of Dr. Natanzi focused on differences between Ms. Katchinski's records and Dr. Natanzi's recitation of those records. See Tr. 155-58. For example, Ms. Katchinski wrote that Ms. Ginsberg "reports getting a flu shot on 1/16/17 and since then has had excruciating throbbing pain in her arm radiating to her neck and down into her hand." Exhibit 2 at 58. However, Dr. Natanzi's summary of this portion of the record says, "Pain in neck and shoulder since the flu shot." Exhibit 19 at 2. The Secretary, therefore, questioned why Dr. Natanzi had omitted the portion of Ms. Katchinski's physical therapy record documenting "pain in her arm radiating to her neck and down into her

[3] It appears that Ms. Ginsberg did not attend all the recommended physical therapy sessions. A February 7, 2017 medical record indicated that Ms. Ginsberg was not interested in continuing physical therapy because she felt that it was not appropriate for her injury. Exhibit 2 at 75.

hand." Tr. 158. The Secretary suggested that "radiating pain" was consistent with a cervical radiculopathy. Id. Dr. Natanzi defended the format of his report by pointing out that he expressed his opinion regarding cervical radiculopathy in another portion of his report.

On redirect examination, Dr. Natanzi discussed Ms. Katchinski's range of motion testing in both shoulders and neck. The active range of motion for Ms. Ginsberg's cervical spine showed some decreases with the decreases being the same on the left and right side. Tr. 229; see also Exhibit 2 at 53-54. Dr. Natanzi opined that this equivalence is inconsistent with a cervical radiculopathy. Tr. 229.

In contrast, the active range of motion testing for Ms. Ginsberg's shoulders showed movements with pain on only the left side. Tr. 229; see also Exhibit 2 at 54. A similar result occurred with the manual muscle test of the right and left shoulders. Ms. Ginsberg was weaker on her left side. Tr. 230; see also Exhibit 2 at 54.

On re-cross examination, the Secretary asked Dr. Natanzi about a different pair of tests. Ms. Katchinski recorded that Ms. Ginsberg's Hawkins-Kennedy and empty can tests were negative. Exhibit 2 at 55. Dr. Natanzi could not explain why these results were negative. Tr. 234. The Secretary suggested that a potential lack of accuracy in administering these tests could imply a lack of accuracy in the range of motion testing. Id.

Dr. Callaghan

In Dr. Callaghan's direct testimony, he emphasized that Ms. Ginsberg reported pain was radiating into the hand and up to the neck. Tr. 273, discussing Exhibit 2 at 52. This presentation is "typical" for cervical radiculopathy according to Dr. Callaghan. Id. Cervical radiculopathy was also the diagnosis of the physical therapist. Id., citing Exhibit 2 at 52.

Ms. Ginsberg reported symptoms consistent with cervical radiculopathy. The quality of pain was listed as throbbing, not burning or numbness. Tr. 274; see also Exhibit 2 at 53. Ms. Ginsberg told the physical therapist that she was having difficulty getting dressed, doing her hair, and shelving books at the library. Exhibit 2 at 53. These are consistent with cervical radiculopathy. Tr. 275.

Dr. Callaghan also discussed the range of motion findings. These showed equal, but restricted, movements. Tr. 275.

Dr. Callaghan acknowledged that some portions of Ms. Ginsberg's experience with the physical therapist were not consistent with cervical radiculopathy. For example, the referral for physical therapy stated that the range of motion in her shoulders was affected. Exhibit 2 at 53; see also Tr. 275. The physical therapist detected tenderness to palpation of the middle deltoid. Exhibit 2 at 55. The physical exam of Ms. Ginsberg was "not completely normal." Tr. 288. These factors are not consistent with cervical radiculopathy. Tr. 276.

Dr. Cagle

Dr. Cagle's testimony concerning Ms. Ginsberg's physical therapy began with Dr. Ionescu's referral. Dr. Ionescu sent Ms. Ginsberg to physical therapy for her neck and shoulder. Exhibit 2 at 53; see also Tr. 349. Ms. Katchinski wrote that the pain is located in the left shoulder and radiating into the hand and up to the neck. Exhibit 2 at 53; see also Tr. 350. Dr. Cagle interpreted this record as showing pain in her entire arm. Tr. 351.

The physical therapist's record states that Ms. Ginsberg reported pain with overhead activities. Exhibit 2 at 52. In Dr. Cagle's view, this presentation is expected from a person with a chronic massive rotator cuff tear. Tr. 355.

With respect to shoulder testing by the physical therapist, Dr. Cagle agreed that Ms. Ginsberg's range of motion was "limited compared to the contralateral side." Tr. 383. A cervical radiculopathy would not explain this limited range of motion. Id.

E. February 2, 2017: Dr. Singh

Medical Record

Ms. Ginsberg saw a neurologist, Dr. Jasjit Singh, on February 2, 2017 for "severe left hand pain and arm pain after having a flu shot about a month and half ago." Exhibit 3 at 9. Dr. Singh evaluated her cervical spine and found that there was tenderness with limited range of motion. Id. Dr. Singh noted that she had "diffuse sensory loss down [her] left upper extremity" and "positive Tinel and Phalen signs" in her left upper extremity. Id.

Dr. Singh ordered studies to evaluate Ms. Ginsberg's condition. A sensory motor nerve conduction velocity study revealed "a mild carpal tunnel syndrome on the right [extremity] and mild to moderate carpal tunnel syndrome on the left [extremity]." Id. Electromyography of both upper extremities revealed "mild denervation of the left abductor pollicis brevis muscles consistent with . . . carpal

tunnel syndrome, more severe on the left than on the right . . . mild denervation of the left biceps brachii muscle consistent with the mild cervical radiculopathy on the left side at the C6 level." Id. at 2. Dr. Singh assessed her with cervical radiculitis, carpal tunnel syndrome, and neuritis secondary to the flu shot. Id. at 10. Dr. Singh referred her to get an MRI of the cervical spine on February 8, 2017. Id.; Exhibit 3 at 5.

Ms. Ginsberg's testimony

Ms. Ginsberg stated that her family doctor recommended that she see a neurologist. Tr. 26. Before this appointment with Dr. Singh, she had not seen a neurologist. Id.

Ms. Ginsberg recalled that Dr. Singh tested her arm and neck. Tr. 27, 46. Ms. Ginsberg did not recall any specifics about the EMG testing. Tr. 46. Although Dr. Singh diagnosed her with "cervical radiculopathy," Ms. Ginsberg did not understand the meaning of this medical terminology. Tr. 47.

Expert Commentary[4]

Dr. Natanzi

Dr. Natanzi emphasized that Dr. Singh reached two diagnoses. Tr. 109. These were "cervical radiculitis" and "neuritis secondary to the flu shot." Exhibit 3 at 9.[5] Of these two, Dr. Natanzi favored "neuritis," as that condition is from the flu vaccination, not cervical radiculopathy. Tr. 108.

In his oral testimony, Dr. Natanzi questioned the reliability of Dr. Singh's EMG. Tr. 111. The gist of Dr. Natanzi's opinion in his oral testimony was that Dr. Singh did not perform all the necessary tests. Tr. 105, 110-11, 187-88.[6]

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[4] The experts extensively testified about Dr. Singh's EMG and cervical MRI, which is discussed in the following section.

[5] More precisely, Dr. Singh diagnosed Ms. Ginsberg with a third condition, carpal tunnel syndrome. However, the presence (or absence) of carpal tunnel syndrome does not affect Ms. Ginsberg's claim that the flu vaccine harmed her shoulder. Tr. 136, 358.

[6] Dr. Natanzi did not disclose an opinion that the EMG testing was incomplete in his report. See Exhibit 19. Without this disclosure, the Secretary could have objected to Dr. Natanzi's testimony. See Simanski v. Sec'y of Health & Hum. Servs., 671 F.3d 1368 (Fed. Cir. 2012). In his oral testimony, Dr. Natanzi explained that his opinion regarding the presence of

Dr. Natanzi also testified that Dr. Singh's examination did not include any signs of cervical radiculopathy. Tr. 187.

Dr. Callaghan

To Dr. Callaghan, Dr. Singh's EMG was "thorough." Tr. 259. Dr. Singh tested many different muscles in both arms. Id. The EMG could exclude a problem in the nerve that corresponds to the bicep muscle. Tr. 288-90. Therefore, the result of the EMG test, an impairment in the motor nerves at the C5-6 level, is likely to be accurate. Tr. 260, 297.[7]

Dr. Cagle

Dr. Cagle's testimony about Ms. Ginsberg's February 2, 2017 appointment with Dr. Singh and the EMG of that date was relatively limited. Dr. Cagle recognized that Dr. Singh reached three diagnoses and one of these three was "neuritis secondary to the flu shot." Tr. 356-58.

F. February 8, 2017: MRI of Cervical Spine

Dr. Singh had referred Ms. Ginsberg for an MRI. She underwent this procedure on February 8, 2017. Exhibit 3 at 5-6.

The radiologist, Ronald Wagner, interpreted the MRI as showing problems from C3 to T2. Id. More specifically, Dr. Wagner found:

- There are posterior annular disc bulges at C4/5 and C5/6 with left foraminal stenosis at C4/5 and bilateral foraminal stenosis at C5/6.
- Broad posterior disc herniations and bony ridging at C5/6 and C-0/7 abutting the ventral surface of the cord and there is bilateral foraminal stenosis and mild stenosis at C5/6 and bilateral foraminal narrowing at C6/7.

Exhibit 3 at 5.

Ms. Ginsberg recalled that the MRI showed she had stenosis in her neck. Tr. 27.

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cervical radiculopathy shifted after he wrote his report because he has testified in more cases involving SIRVA and he looked at the results of Ms. Ginsberg's EMG again. Tr. 186.

[7] "Specificity" is a term used to measure the value of a positive test. Tr. 262.

Both Dr. Natanzi and Dr. Callaghan testified that Ms. Ginsberg's cervical spine was affected by degenerative (or age-related) changes. Tr. 112, 277. They also agreed that Ms. Ginsberg's problem in her cervical spine was worse on her left side. Tr. 112, 260.

G. February 27, 2017: Dr. Singh

Medical Record

On February 27, 2017, Ms. Ginsberg had a follow-up appointment with Dr. Singh. Exhibit 3 at 7. At this visit, Dr. Singh reviewed the February 8, 2017 MRI, showing multilevel disc abnormalities. Id. Dr. Singh stated that the MRI explained Ms. Ginsberg's pain radiating down her left upper extremity. Id. at 7. Dr. Singh noted that Ms. Ginsberg, however, insisted that "the pain [was] coming from the flu shot. Id. at 8.

Dr. Singh's assessment included "cervical radiculitis." Exhibit 3 at 8. He also wanted to rule out an internal derangement in her left shoulder. Id. He suggested that Ms. Ginsberg obtain an MRI of her left shoulder and consult an orthopedist. Id. Dr. Singh added that Ms. Ginsberg "is not comfortable with my explanation to her." Id.

Ms. Ginsberg's Testimony

Ms. Ginsberg recognized that after the cervical MRI, Dr. Singh had told her that her pain was coming from her cervical spine. Tr. 47. She has reservations about Dr. Singh's treatment of her. Tr. 72.

Expert Commentary

Dr. Natanzi

With respect to Dr. Singh's treatment on February 27, 2017, Dr. Natanzi made essentially three points. First, Dr. Natanzi acknowledged that Dr. Singh had stated that Ms. Ginsberg's pain was due to problems in her cervical spine / discs. Tr. 115, 161, 178. Next, Dr. Natanzi seemed to question the thoroughness of Dr. Singh's evaluation, stating that Dr. Singh appeared not to have examined Ms. Ginsberg's shoulder[8] and did not conduct any special tests like a Spurling

[8] The record suggests that Dr. Singh did examine Ms. Ginsberg's shoulder, as he "Rule[d] out left shoulder internal derangement" and noted that she had "limited range of motion in the upper left extremity." Exhibit 3 at 8.

maneuver. Tr. 116-17. Last, Dr. Natanzi inferred that because Dr. Singh referred Ms. Ginsberg to an orthopedist, Dr. Singh must have thought that the cervical radiculopathy was not explaining everything. Tr. 179.

Dr. Callaghan

Dr. Callaghan's opinion regarding Dr. Singh's conclusions was succinct. Dr. Callaghan stated that Dr. Singh, a neurologist, diagnosed cervical radiculopathy. Tr. 269, 276. Dr. Callaghan acknowledged that Dr. Singh referred her to an orthopedist but Dr. Callaghan did not know the reason for the referral. Id.

Dr. Cagle

Dr. Cagle, arguably, provided some insight as to why Dr. Singh might have referred Ms. Ginsberg to an orthopedist. According to Dr. Cagle, patients may request other evaluations. Tr. 359. Dr. Singh's memorialization that Ms. Ginsberg does not agree with his assessment is a subtle point, suggesting that the referral to an orthopedist originated with Ms. Ginsberg, not Dr. Singh. Id.

H. March 8, 2017 through April 11, 2017: Dr. McCormack and Physical Therapy

Medical Records

From March 2017 to June 2017, Ms. Ginsberg saw Richard McCormack, an orthopedist, for left shoulder pain three times. Exhibit 4 at 2; Exhibit 5 at 7-9. In the first appointment, Ms. Ginsberg described the pain as "throbbing and stabbing." Exhibit 4 at 2 (March 8, 2017). Ms. Ginsberg had positive empty can, Neer, and Hawkins tests. Id. at 2. Dr. McCormack diagnosed Ms. Ginsberg with left deltoid bursitis and recommended her to resume physical therapy for "cuff strengthening [and] modalities."[9] Id. at 3.

Ms. Ginsberg underwent a second round of physical therapy from March 15, 2017 to April 11, 2017. Exhibit 2 at 95-97. However, this set of physical therapy appointments appear not to contribute to assessing whether the flu vaccine harmed Ms. Ginsberg's shoulder as the experts did not discuss this set.

Ms. Ginsberg's Testimony

[9] An April 11, 2017 medical record shows that Ms. Ginsberg attended a total of three physical therapy sessions before discontinuing treatment for the second time. Exhibit 2 at 95-97.

Ms. Ginsberg stated that Dr. McCormack is a general orthopedist. Tr. 48. When she saw Dr. McCormack, Ms. Ginsberg was having radiating pain going from her shoulder down to her arm. Tr. 49. Dr. McCormack took an X-ray, stated that she had bursitis, and sent her to physical therapy. Tr. 28. During March 2017, Ms. Ginsberg did exercises with a towel at home. Tr. 29.

Expert Commentary

Dr. Natanzi and Dr. Cagle

Dr. Natanzi and Dr. Cagle assessed Dr. McCormack's March 2, 2017 report differently. (Dr. Callaghan did not provide any meaningful testimony about this piece of evidence.)

Dr. Natanzi emphasized Dr. McCormack's diagnosis of bursitis, calling it "spot on." Tr. 118. The bursa is a pad or cushion under the deltoid muscle and above the rotator cuff. Id. Inflammation of the bursa is known as "bursitis." Dorland's Illus. Med. Dict. 260 (33rd ed. 2020). In Dr. Natanzi's opinion, the bursa is "vaccine-sensitive," and the location of many shoulder injuries induced by vaccine administration. Tr. 118.

In contrast, Dr. Cagle did not agree with the diagnosis of bursitis. Dr. Cagle stated that the correct diagnosis is a rotator cuff tear. Tr. 363.

I. May 24, 2017: Dr. McCormack

On May 24, 2017, Ms. Ginsberg returned to Dr. McCormack. She complained about pain in her left shoulder, which was not radiating and was "dull, throbbing, and burning." Exhibit 5 at 8. She also reported that since the previous visit, she had improved. Id. As part of an examination of Ms. Ginsberg's left shoulder, Dr. McCormack reported positive empty can and Neer tests and a negative Hawkins test. Id. at 8.

Dr. McCormack ordered a left shoulder MRI. Exhibit 5 at 8. The purpose was to rule out a potential tear in her rotator cuff. Id.

There was relatively little meaningful testimony from the experts about this visit with Dr. McCormack. The experts focused on the results of the left shoulder MRI.

J. May 25, 2017: Left Shoulder MRI

Medical Record

Ms. Ginsberg underwent an MRI for her left shoulder on May 25, 2017. Exhibit 5 at 13. The MRI revealed several problems including:

> 1. Full-thickness tearing of the distal supraspinatus and infraspinatus tendons and surrounding bursitis . . . without evidence of tendon retraction or muscle atrophy.
> 2. Partial tearing of the subscapularis tendon.
> 3. Biceps tenosynovitis.
> 4. Glenohumeral joint effusion.
> 5. AC joint arthrosis.

Id.

Expert Commentary

Dr. Natanzi

Dr. Natanzi explained some of the shoulder's anatomy. The supraspinatus tendon is on top of the shoulder. The infraspinatus tendon originates from the person's back. The subscapular tendon originates from the person's front. Each tendon is approximately one centimeter thick. Tr. 180-82.

In Dr. Natanzi's opinion, the tears to the supraspinatus tendon and the infraspinatus tendon were "caused by the vaccine needle." Tr. 122. Later, Dr. Natanzi testified that the full tears to these two tendons "were made symptomatic because of the vaccine. I can say that definitively." Tr. 194. He continued: "If there was a partial tear there before, I don't know, but I can tell you . . . the symptomization of the rotator cuff tear was also caused by the vaccine." Id.

With respect to the bursitis that accompanied the tears in two rotator cuff tendons, Dr. Natanzi stated: "I can say definitively that the bursitis in entirety was caused by the vaccine." Tr. 194. He equated "bursitis" as a classic SIRVA finding. Tr. 122. Ms. Ginsberg's bursitis is "100 percent attributable to the vaccine, especially given the clinical context, how she presented right away with a bursitis." Id.

Dr. Natanzi explained bursitis in more detail. Bursitis in the shoulder can develop acutely, such as for baseball pitchers. Tr. 185. In theory, some bursitis

could be chronic, although Dr. Natanzi tends not to use the term "chronic bursitis." Instead, Dr. Natanzi describes some problems as chronic tendinitis. Tr. 186. Ms. Ginsberg's MRI did not show any signs of an acute trauma, like swelling. Tr. 190. A lack of acuteness did not matter to Dr. Natanzi's opinion because the MRI was performed months after the vaccination. Id. A final point about bursitis was that the radiologist did not quantify the degree of bursitis. Tr. 183-84.

For the AC joint arthritis, Dr. Natanzi stated that this deterioration reflects a chronic problem due to wear and tear. Tr. 121, 182. The vaccine did not cause arthritis in the AC joint. Tr. 182.

Dr. Cagle

Dr. Cagle agreed with some portions of Dr. Natanzi's testimony regarding bursitis. The term "bursitis" is not very descriptive. Tr. 400. Bursitis can be acute or chronic. Tr. 400. Although Ms. Ginsberg's MRI did show bursitis, the MRI did not show any acute pathology in the shoulder. Tr. 338, 396, 399. Because Ms. Ginsberg shoulder problem was not acute, Dr. Cagle tended to think of the problem as "chronic," meaning it had lasted longer than six weeks. Tr. 387.

As to relationship between the bursitis and the rotator cuff tears, Dr. Cagle disagreed with Dr. Natanzi. Dr. Cagle stated that the MRI revealed a "massive" tear. Tr. 324.[10] Massive rotator cuff tears are likely to cause dysfunction at some time. Tr. 325.

Dr. Natanzi testified that around fifty percent of people over 50 years old who have rotator cuff tears do not have problems or symptoms. Tr. 112-13, 191-92. Dr. Cagle did not know why Ms. Ginsberg's (assumed) rotator cuff tear became symptomatic after the vaccination. Tr. 365.

Regardless of the reason the rotator cuff tear became noticeable, the rotator cuff tear is the reason for the bursitis. In Dr. Cagle's opinion, looking at Ms. Ginsberg's bursitis is missing the forest for the trees. Tr. 364. The pathology that should be treated is the rotator cuff tears. Tr. 363.

[10] Dr. Cagle stated that a system classifies tears in two tendons as "massive." Tr. 324. Although the term "massive" sounds "grandiose," this label is appropriate in Ms. Ginsberg's case.

Finally, Dr. Cagle agreed with Dr. Natanzi's assessment of the arthritis in the AC joint. That problem is consistent with wear and tear of tendon for many years. Tr. 325.

K. June 14, 2017: Dr. McCormack

Medical Record

After the MRI on her left shoulder, Ms. Ginsberg returned to Dr. McCormack on June 14, 2017. Exhibit 5 at 9-10. Ms. Ginsberg had pain in her left shoulder, which she rated as a 4 out of 10 and for which she was not taking any medication. Id. at 9. "The pain does not radiate and is described as throbbing." Id.

Upon examination, Ms. Ginsberg was found to have almost normal strength throughout her left shoulder. Id. at 9-10. The empty can test and the Neer test were positive. Id. at 11. The Hawkins test was negative. Id.

Dr. McCormack recommended that Ms. Ginsberg undergo an operation. Exhibit 5 at 10. He noted that Ms. Ginsberg was "not interested at this time." Id.; accord Tr. 30 (Ms. Ginsberg's testimony).

Expert Commentary

The experts had relatively little to say about the June 14, 2017 appointment with Dr. McCormack. Dr. Natanzi stated that Dr. McCormack's plan for a surgery shows that there is a problem in Ms. Ginsburg's shoulder. Tr. 124, 217. Dr. Cagle pointed out that Ms. Ginsberg had surprisingly good range of motion and strength despite the tears. Because of this functioning, Dr. Cagle would not have offered an operation. Tr. 371-72.

L. October 2017: Second Opinions from Dr. Tinker

Medical records

Ms. Ginsberg sought a second medical opinion for her condition from another orthopedist, Jonathan Ticker. During her first appointment on October 16, 2017, Ms. Ginsberg described the duration of her pain and present characteristics. Exhibit 7 at 4. Dr. Ticker reviewed both the reports and the films of the left shoulder MRI. However, Dr. Ticker was "not convinced about the tear." Id. at 5. Dr. Ticker examined Ms. Ginsberg's shoulder and detected "mild" pain at the end of the range of motion. Id. at 4. Dr. Ticker also performed a Spurling test on Ms.

Ginsberg's neck and the result was negative. Id. at 5. Dr. Ticker diagnosed her with a left rotator cuff tear and wrote that a "repeat MRI is clearly indicated." Id. at 5.

The second MRI revealed advanced supraspinatus and infraspinatus tendinosis with a mild to moderate partial-thickness articular sided tear at the junction of the tendons, mild infraspinatus tendinosis, moderate AC joint arthrosis and subacromial/subdeltoid bursitis. Exhibit 5 at 12 (Oct. 18, 2017).

At a follow-up exam on October 21, 2017, Dr. Ticker discussed the October 18, 2017 MRI with Ms. Ginsberg. Dr. Ticker advised Ms. Ginsberg to take Medrol, return to physical therapy, and consider an injection. Exhibit 7 at 2. If these methods failed, Dr. Ticker suggested surgery as an option. Id.

Expert Commentary

Dr. Natanzi commented that Dr. Ticker twice looked for evidence of nerve compression via the Spurling test, but twice these results were negative. Tr. 106.

Dr. Cagle interpreted the two MRIs as being fundamentally the same with the second one showing some advanced tendinosis. Tr. 326-27. Dr. Cagle also noted that Dr. Ticker did not recommend surgery as an immediate next step. Tr. 401-02.

M. Current Status

Ms. Ginsberg did not seek additional treatment after this appointment with Dr. Ticker. Tr. 35, 53. Her pain has resolved, except for a few episodes each month. Tr. 50. She has returned to exercising at a gym. Tr. 34.

II. Procedural History

Ms. Ginsberg initiated a claim in the National Vaccine Injury Compensation Program by filing a petition on February 8, 2019. She alleged that she suffered from SIRVA as a result of receiving the flu vaccine on January 9, 2017. She filed medical records and confirmed that the record was complete on February 14, 2019. This statement of completion was subsequently amended on July 1, 2019 and then again on April 8, 2020.

The Secretary contended that the medical evidence did not support petitioner's allegation and recommended that compensation be denied. Resp't's Rep., filed July 22, 2020. Specifically, the Secretary argued that Ms. Ginsberg's

SIRVA did not meet the regulatory definition of SIRVA, as defined on the Vaccine Injury Table. Id. at 3. Her pain was not limited to the left shoulder in which the vaccine was injected, as the pain had consistently radiated down her left arm. Id. at 4. Furthermore, a February 2017 MRI of her cervical spine revealed multilevel disc abnormalities that explain a cause for her left shoulder pain. Id. The Secretary was uncertain whether there was a claim for causation-in-fact but still addressed it. If a claim for causation-in-fact were alleged, the Secretary maintained that Ms. Ginsberg failed to show her alleged injury more likely than not resulted from the flu vaccine. Id.

The case was reassigned to the undersigned on January 21, 2021. A status conference was held on February 25, 2021 to discuss upcoming deadlines for filing expert reports.

Ms. Ginsberg filed a report from a pain specialist whom she had retained, Dr. Naveed Natanzi, on March 9, 2021. Exhibit 19. The Secretary responded by submitting a report from an orthopedist whom he had retained, Dr. Paul Cagle, on May 27, 2021 and a report from a neurologist whom he had retained, Dr. Brian Callaghan, on June 14, 2021. Exhibits A and C. Thereafter, Ms. Ginsberg presented a supplemental expert report from Dr. Natanzi on July 23, 2021 (Exhibit 34) and the Secretary submitted a supplemental expert report from Dr. Cagle on September 20, 2021 (Exhibit D).

At the October 12, 2021 status conference, both parties discussed their experts' disagreement on the diagnostic usefulness of empty can, Hawkins, and Neer's maneuver. Despite this disagreement, both parties advised that the expert report phase had concluded and that they were ready to proceed to the briefing stage. The briefing instructions were issued on October 28, 2021. Afterwards, Ms. Ginsberg filed an amended petition, asserting an off-table shoulder injury claim in addition to her on-table SIRVA claim.

A November 8, 2021 order directed respondent to file an amended Rule 4(c) Report, which the Secretary filed on November 22, 2021. The Secretary construed the November 8, 2021 order as requiring a discussion on the 48-hour onset criteria and hence focused on this issue in the Rule 4(c) Report. Am. Resp't's Rep at 1 n.2.

On January 5, 2022, Ms. Ginsberg filed a brief in support of a ruling on the record. On March 7, 2022, the Secretary submitted his brief along with a supplemental expert report from Dr. Cagle. On April 6, 2022, Ms. Ginsberg filed a reply brief.

A review of the parties' briefs revealed that Ms. Ginsberg had not filed medical records created close in time to the vaccination. She was, therefore, directed to obtain those records. Order, issued Nov. 2, 2022. Ms. Ginsberg submitted a critical record from Dr. Ionescu, which was handwritten. Exhibit 42. She later obtained a transcription. Exhibit 43.

Dr. Ionescu's record from 10 days after the vaccination was a primary basis for finding that Ms. Ginsberg developed shoulder pain within 48 hours of her vaccination. Tentative Finding, issued June 12, 2023. Due to other disputes among the experts, the case was scheduled for a hearing. Order, issued July 12, 2023.

The hearing was held in two sessions. Ms. Ginsberg testified on November 7, 2023 via videoconferencing. Another session was held on November 29-30, 2023, in Ann Arbor, Michigan. Dr. Natanzi, Dr. Cagle, and Dr. Callaghan testified in accord with their reports.

After the hearing, Ms. Ginsberg requested an opportunity to argue her case through a post-hearing brief. She did so on April 12, 2024. The Secretary responded on May 28, 2024. Ms. Ginsberg spoke last. Pet'r's Reply, filed July 11, 2024. With the submission of the reply brief, the case is ready for adjudication.

III. Standards for Adjudication

A petitioner is required to establish her case by a preponderance of the evidence. 42 U.S.C. § 300aa-13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing a special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with the dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

IV. On-Table Claim

The Vaccine Injury Table associates the flu vaccine with a shoulder injury related to vaccine administration. 42 C.F.R. § 100.3. The regulations further define "SIRVA":

> SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (*e.g.* tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time-frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (*e.g.* NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

Here, the presence of cervical radiculopathy prevents Ms. Ginsberg from meeting the regulatory definition of SIRVA. See, e.g., Durham v. Sec'y of Health & Hum. Servs., No. 17-1899V, 2023 WL 3196229, at *13-15 (Fed. Cl. Spec. Mstr.

May 2, 2023); Humbert v. Sec'y of Health & Hum. Servs., No. 17-360, 2023 WL 2565729, at *19 (Fed. Cl. Spec. Mstr. Feb. 22, 2023); Truett v. Sec'y of Health & Hum. Servs., No. 17-1772V, 2022 WL 17348386, at *16-21 (Fed. Cl. Spec. Mstr. Nov. 1, 2022); Colbert v. Sec'y of Health & Hum. Servs., No. 18-166V, 2022 WL 2232210, at *17 (Fed. Cl. Spec. Mstr. May 27, 2022).

Although Ms. Ginsberg is not entitled to compensation for an on-Table SIRVA claim, she might remain entitled to compensation for an off-Table claim. That alternative path to recovery is addressed next.

V. Off-Table Claim

When pursuing an off-Table injury, a petitioner bears a burden "to show by preponderant evidence that the vaccination brought about [the vaccinee's] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

In Ms. Ginsberg's case, there is no meaningful dispute regarding the first Althen prong and the third Althen prong. Dr. Cagle agreed that vaccinations can cause shoulder injuries. Tr. 344. He also stated that the appropriate temporal window between the vaccination and the onset of shoulder pain might extend to 10 days. Tr. 399.[11] Consequently, the controversy concerns the second Althen prong.

The Federal Circuit has elaborated on the significance of this element:

> The second prong of the Althen III test is not without meaning. There may well be a circumstance where it is found that a vaccine can cause the injury at issue and where the injury was temporally proximate to the vaccination, but it is illogical to conclude that the injury was actually caused by the vaccine.

Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1327 (Fed. Cir. 2006).

[11] Dr. Cagle recognized that limiting SIRVA cases to an onset of 48 hours helps legally. However, from a medical perspective, he questioned this limitation. Tr. 407.

In opposing Ms. Ginsberg's claim that the January 9, 2017 flu vaccination harmed her, the Secretary posits two other explanations for Ms. Ginsberg's shoulder problems: a pre-existing cervical radiculopathy and age-related tears in her rotator cuff. See Resp't's Posthear'g Br. at 15-16. In the Secretary's view, the flu vaccination played no role.

The Secretary's arguments do not measure up. The Secretary is effectively saying that Ms. Ginsberg had a cervical radiculopathy for which there is no evidence of her receiving any medical treatment until after the flu vaccination and Ms. Ginsberg had chronic rotator cuff problems for which there is no evidence of her receiving any medical treatment until after the flu vaccination. Then, coincidentally after the flu vaccination, she started to manifest problems of her previously silent cervical radiculopathy. Concomitantly, coincidentally after the flu vaccination, she started to manifest problems of her previously silent rotator cuff problems. This argument overemphasizes the role of coincidences.

Instead, Ms. Ginsberg meets her burden of proof to establish a logical sequence of cause and effect between the flu vaccination and her shoulder pain. Ms. Ginsberg emphasizes the acuteness of her injury. See Pet'r's Reply at 4-7. Although a sequence of events in which a vaccination preceded the onset of an injury does not always mean that the vaccination caused the injury, the sequence of events, statements from medical professionals, and Dr. Natanzi's opinion are sufficient to carry the day for Ms. Ginsberg.

Accordingly, Ms. Ginsberg is entitled to compensation.[12]

VI. Compensation

Before the hearing, the parties disputed the amount of compensation that was reasonable for Ms. Ginsburg's pain and suffering. The foundation for the parties' arguments was the written evidence, including medical records, affidavits, and expert opinions. The undersigned determined that this record supported an award of $40,000 in compensation for past pain and suffering and no compensation was appropriate for future pain and suffering.

The oral testimony produced some evidence that arguably might have affected the amount of compensation. However, the evidence tended to confirm

[12] Although in theory the Secretary might attempt to prove an alternative factor caused Ms. Ginsberg's shoulder problem, the Secretary has declined. See Resp't's Prehear'g Br. at 27.

that an award of $40,000 as compensation for Ms. Ginsberg's past pain and suffering was reasonable.

Ms. Ginsberg's pain due to the vaccination was limited both anatomically and temporally. Anatomically, Ms. Ginsberg did not persuasively refute the opinion of her treating doctors and Dr. Callaghan that she had a problem in her neck. The presence of a cervical radiculopathy does not preclude a petitioner, like Ms. Ginsberg, from also incurring a shoulder injury that was caused-in-fact by the vaccination. Ms. Ginsburg recognizes that her "cervical radiculopathy was not caused by the vaccination." Pet'r's Prehear'g Br., filed Jan. 5, 2022, at 17. Similarly, the arthritis in Ms. Ginsberg's acromioclavicular joint and partial tearing in the subscapularis tendon were not, by Dr. Natanzi's testimony, caused by the vaccination. Tr. 121-22.

The duration of Ms. Ginsberg's vaccine-related shoulder pain was also limited. Ms. Ginsberg stated that she does not currently have pain, except for occasional throbbing for which she takes ibuprofen. Tr. 31, 34-35, 50-51. She has returned to exercising in a gym and lifting light weights. Tr. 34.

This evidence tends to show that the degree of Ms. Ginsberg's pain and suffering was relatively mild. As such, compensation in the amount of $40,000 for past pain and suffering is reasonable. Furthermore, Ms. Ginsberg is not claiming lost earnings and is not claiming unreimbursed expenses. Tr. 36.

VII. Conclusion

Ms. Ginsberg has established with preponderant evidence that the flu vaccine caused an injury to her shoulder. As such, she is entitled to compensation. A reasonable amount of compensation for this injury is $40,000.

The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for review, including the deadline, can be found in the Vaccine Rules, which are available on the website for the Court of Federal Claims.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master